UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

IN RE: DEPUY ORTHOPAEDICS, INC. PINNACLE DEVICE IMPLANT PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. 3:11-MD-2244-K

This Document relates to:

KENNETH DOYLE LYNCH and NANCY LYNCH,

Plaintiffs,

vs.

DEPUY ORTHOPAEDICS, INC., DEPUY PRODUCTS, INC., DEPUY INTERNATIONAL LIMITED, JOHNSON & JOHNSON, and JOHNSON & JOHNSON SERVICES, INC.,

Defendants.

Civil Action No. 3:15-cv-

COMPLAINT AND DEMAND FOR JURY TRIAL

COMPLAINT FOR DAMAGES

Plaintiffs KENNETH DOYLE LYNCH and NANCY LYNCH ("Plaintiffs") allege, upon information and belief, against DEPUY ORTHOPAEDICS, INC., DEPUY PRODUCTS, INC., DEPUY INTERNATIONAL LIMITED, JOHNSON & JOHNSON, and JOHNSON & JOHNSON SERVICES, INC., ("Defendants"), the following:

SUMMARY OF PLAINTIFFS' ALLEGATIONS

1. This is an action for damages suffered by Plaintiffs as a direct and proximate result of Defendants' wrongful conduct in connection with the development, design, testing, manufacture, distribution, and sale of the DePuy PINNACLE™ Acetabular Cup and the PINNACLE™ Device Replacement System ("Pinnacle Device"). As a result of the inadequate testing of the Pinnacle Device that was sold by Defendants and implanted in Plaintiff KENNETH

DOYLE LYNCH, Plaintiff has suffered, and continues to suffer, serious bodily injury and has incurred, and continues to incur, medical expenses to treat Plaintiff's injuries and condition.

PARTIES

2. Plaintiffs, KENNETH DOYLE LYNCH and NANCY LYNCH, were, and at all times relevant to this Complaint are, residents of the State of Texas and reside in New Boston, Texas.

3. Defendant DEPUY ORTHOPAEDICS, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY ORTHOPAEDICS, INC. is, and was at all times relevant herein, doing business in and/or having directed its activities to Texas.

4. Defendant DEPUY PRODUCTS, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY PRODUCTS, INC. is, and was at all times relevant herein, doing business in and/or having directed its activities to Texas.

5. Defendant DEPUY INTERNATIONAL, LIMITED is, and at all times relevant to this Complaint was, a British Limited Partnership with its principal place of business at St. Anthony's Road, Beeston, Leeds, West Yorkshire, United Kingdom. Defendant DEPUY INTERNATIONAL, LIMITED is, and was at all times relevant herein, doing business in and/or having directed its activities to Texas.

6. Defendant JOHNSON & JOHNSON SERVICES, INC. is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON SERVICES, INC. is, and was at all times relevant herein, doing business in and/or having directed its activities to Texas.

7. Defendant JOHNSON & JOHNSON is, and at all times relevant to this Complaint was, a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON is, and was at all times relevant herein, doing business in and/or having directed its activities to Texas.

8. At all times relevant herein, Defendants transacted, solicited, and conducted business in the State of Texas and derived substantial revenue from such business.

9. At all times relevant herein, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, advertising, promoting, marketing, distributing, labeling, and/or selling the subject product.

10. At all times relevant herein, Defendants expected, or should have expected, that its acts would have consequences within the United States, and in Texas, in particular.

11. At all times relevant herein, Defendants were the agents of each other, and through their actions, as alleged herein, each Defendant was acting within the course and scope of its agency and was subject to and under the supervision of its Co-Defendants.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332 because Plaintiffs and Defendants are citizens of different states and the amount in controversy exceeds $75,000, exclusive of costs and interest.

13. Venue in this action properly lies in the Eastern District of Texas pursuant to 28 U.S.C. § 1391 (a) and (c). Venue also properly lies in the Northern District of Texas pursuant to Case Management Order No. 1 in IN RE: DePuy Orthopaedics, Inc. Pinnacle Device Implant Products Liability Litigation, MDL. No. 2244.

FACTUAL BACKGROUND

14. The Pinnacle Device was developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), fracture, and other degenerative conditions. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis). In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.

15. The Pinnacle total hip replacement system consists of four components: (1) a metal femoral stem, (2) a femoral head (or ball), and (3) a liner, and (4) an acetabular cup. The metal femoral stem is inserted inside the femur bone, the metal femoral head connects to the top of the stem, and then makes contact with a liner that is attached to the interior portion of the metal acetabulum cup (socket). The acetabulum cup is comprised of titanium metal. Either a plastic, ceramic, or cobalt-chromium metal liner is then placed on the inside of the acetabulum cup. The metal femoral head rotates within the plastic, ceramic, or metal liner, depending upon which liner the surgeon selects based upon the patient's needs. The cobalt-chromium metal liner is branded by Defendants as the "Ultamet" and/or the Pinnacle metal insert. The Pinnacle Device with the Ultamet liner, and/or a Pinnacle metal insert is the "metal-on-metal" device due to the fact that both are articulating surfaces, in that the femoral head (ball) and acetabulum liner (socket) are comprised of cobalt-chromium metal.

16. Defendants did not seek premarket approval from the FDA, and thus the FDA made no finding that the Pinnacle Device was safe or effective for the product's intended purpose.

17. The Pinnacle Device is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

18. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Device, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

19. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

20. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

21. A medical device on the market prior to the effective date of the MDA — a so-called "grandfathered" device — was not required to undergo premarket approval.

22. In addition, a medical device marketed *after* the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (*i.e.*, a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to

notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then clear the new device for sale in the United States.

23. The MDA does not require an FDA determination that the device is in fact, substantially equivalent to a grandfathered device.

24. Instead of assuring the safety of the Pinnacle Device through clinical trials, DePuy sought to market its Pinnacle Device without conducting any clinical trials by obtaining FDA approval under section 510(k). To that end, Defendants submitted a section 510(k) premarket notification of intent to market the Pinnacle Device.

25. By telling the FDA that the Pinnacle Device's design was "substantially equivalent" to other hip products on the market, DePuy was able to avoid the safety review required for premarket approval under FDA regulations including clinical trials.

26. The FDA approved the Pinnacle Device for sale by means of the abbreviated 510(k) process and consequently, the FDA did not require the Pinnacle Device to undergo clinical trials.

27. The 510(k) notification for the Pinnacle Device includes only Defendant DePuy's assertion that it believes the DePuy Pinnacle Device to be substantially equivalent to devices that themselves had never been reviewed for safety and effectiveness.

28. Significantly, unlike the premarket approval process, the 510(k) notification process does not call for scrutiny — or even clinical testing — of a device's safety and effectiveness.

29. A finding of substantial equivalence is not equivalent to a finding of a device's safety and effectiveness. This point is forcefully underscored by the FDA's letter to DePuy,

which says nothing about the safety and effectiveness of the Pinnacle Device; finds only that the device was "substantially equivalent to devices introduced into interstate commerce prior to May 28, 1976"; and concludes by stressing that the agency's determination of substantial equivalence "does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies."

30. Thus, the FDA's finding of "substantial equivalence" had nothing to do with reviewing the Pinnacle Device's safety and effectiveness, but rather only a determination of equivalence to devices that underwent no safety and effectiveness review.

31. While most hip replacements use a polyethylene plastic acetabular liner, DePuy's Pinnacle Device has a critical difference: it uses a metal acetabular liner. By using a metal acetabular liner and a metal femoral ball, the Pinnacle Device forces metal to rub against metal with the full weight and pressure of the human body. Because of Defendants' defective design for the Pinnacle Device, hundreds of patients — including Plaintiff — have been forced to undergo surgeries to replace the failed hip implants.

32. Plaintiffs believe that the Pinnacle Device suffers from a similar design or manufacturing defect that forced DePuy to recall over 93,000 metal-on-metal ASR and ASR XL hip implants. While the exact nature of the common defect is still being investigated, Plaintiffs believe that both hip implants suffer from one or more similar design or manufacturing defects that cause excessive amounts of cobalt and chromium to wear from the surface of the acetabular insert or from the femoral head. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

33. Not long after DePuy launched the Pinnacle Device, reports of failures began flooding into DePuy. For example, on May 4, 2002, DePuy received a complaint that a patient had to undergo a surgery to remove and replace the hip implant because the liner disassociated with the cup. DePuy closed its investigation of this complaint, finding that "corrective action is not indicated." Two weeks later, on May 17, 2002, DePuy received another report that another patient had to undergo surgery to remove and replace a defective hip implant because the acetabular cup had loosened. Again, DePuy closed its investigation of this complaint, finding that "corrective action is not indicated."

34. Over the next two years, reports that the Pinnacle Device had failed were flooding into DePuy. For example, by the end of 2008, DePuy had received more than 430 reports and by the end of 2009, the number had skyrocketed to almost 750. To date, DePuy has received an astonishing 1,300 reports associated with Pinnacle Devices.

35. Despite its knowledge that the Pinnacle Device had a defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, DePuy continued to sell the defective hip implant. In so doing, DePuy actively concealed the known defect from doctors and patients — including Plaintiff and Plaintiff's doctor — and misrepresented that the Pinnacle Device was a safe and effective medical device.

36. DePuy's reasons for concealing the defect with its Pinnacle Device are clear. In 2009 alone, DePuy brought in more than $5.4 billion in sales. Hip implant sales are critically important to DePuy's parent company, J&J, and DePuy is one of J&J's most profitable business groups. In 2008, DePuy was faced with a critical defect in one of its hip implant systems. The last thing DePuy wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, DePuy decided that it would

not issue an embarrassing recall when it learned of the defects with its Pinnacle Device. Moreover, motivated by greed rather than patient safety, DePuy did not even stop selling the Pinnacle Device. Instead, it continued to manufacture the hip implants and it continued to sell them to unsuspecting patients like Plaintiff. To this day DePuy continues to sell these defective implants to unsuspecting patients without any warning about the risks or the failures that had been reported to the company.

37. On or about April 18, 2007, Plaintiff underwent a total hip replacement procedure on his right hip, performed by Dr. Gregory J. Smolarz at St. Michael Health Care Center in Texarkana, Texas. Dr. Smolarz implanted a Pinnacle Device in place of Plaintiff's right hip.

38. By this time, Defendants had already received over 600 reports that the Pinnacle Device had failed, and they knew that the product was defective, but Defendants refused to disclose that information to Plaintiff, his physicians or the public.

39. After a period of time following the hip replacement surgery, Plaintiff began to experience pain in his right hip area. Plaintiff sought consultation with Dr. Smolarz in this regard who examined Plaintiff and ordered hip-related testing.

40. Plaintiff continues to receive medical treatment for his ongoing right hip pain.

41. Several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent an original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost four times more likely to suffer from a hip dislocation than those who have not. (Phillips CB, *et al*. Incidence rates of

dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20-26.).

42. As a direct and proximate result of the failure of Plaintiff's defective Pinnacle Device and the Defendants' wrongful conduct, Plaintiff sustained and continues to suffer economic damages (including medical expenses), severe injuries, pain, suffering and emotional distress. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the $75,000 jurisdictional minimum of this court.

43. As a direct and proximate result of the failure of the defective Pinnacle Device and Defendants' wrongful conduct, Plaintiff has been caused economic damages, grief, sorrow, mental anguish, emotional distress, and pain and suffering.

CAUSES OF ACTION

First Cause of Action
Negligence
(Against All Defendants)

44. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

45. Defendants at all times mentioned had a duty to exercise reasonable care in the design, manufacture, testing, inspection, packaging, labeling, distribution, marketing, examination, maintenance and sale of the DePuy Pinnacle Device to ensure that it would be safely used in a manner and for a purpose for which it is made.

46. Defendants at all times mentioned knew or in the exercise of reasonable care should have known, that the Pinnacle Device was of such a nature that it was not properly designed, manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with the proper warnings, and was unreasonably likely to injure the Pinnacle Device users.

47. Defendants negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine, and supplied the Pinnacle Device, such that it was dangerous and unsafe for the use and purpose for which it was intended.

48. Defendants were aware of the probable consequences of the Pinnacle Device. Defendants knew or should have known that the Pinnacle Device would cause serious injury; they failed to disclose the known or knowable risks associated with the Pinnacle Device. Defendants willfully and deliberately failed to avoid those consequences, and in doing so, Defendants acted in conscious disregard of the safety of Plaintiff.

49. Defendants owed a duty to Plaintiff to adequately warn Plaintiff and Plaintiff's treating physicians of the risks associated with the Pinnacle Device and the resulting harm and risk it would cause patients.

50. Defendants breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Pinnacle Device.

51. As a direct and proximate result of the duties breached, the Pinnacle Device used in Plaintiff's hip surgery failed, resulting in great suffering, pain and harm.

52. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered injuries and damages.

53. Defendants' conduct in continuing to market, sell and distribute the Pinnacle Device after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others

justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

WHEREFORE, Plaintiffs request a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court, together with costs and interest on that amount at the legal rate from the date of judgment until paid, and other such relief this Court deems just and appropriate.

Second Cause of Action
Strict Products Liability (Manufacturing Defect)
(Against all Defendants)

54. Plaintiffs re-allege and incorporate by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

55. Defendants designed, manufactured, assembled, distributed, conveyed and/or sold the DePuy Pinnacle Device, including the Pinnacle acetabular cup, the Pinnacle metal liner and the metal-on-metal femoral head.

56. The Pinnacle Device is defective, and fails to perform safely and effectively for the purpose for which it was originally designed.

57. At all times material hereto, the DePuy Pinnacle Device that was designed, manufactured, promoted, distributed, marketed, and sold by the Defendants was expected to reach, and did reach, prescribing physicians and consumers, including Plaintiff, without substantial change in the condition in which it was sold.

58. Plaintiff and Plaintiff's doctor used the DePuy Pinnacle Device as directed for its intended purpose.

59. The Pinnacle Device implanted into Plaintiff was being used in a manner reasonably anticipated at the time it was implanted in Plaintiff's hip by Plaintiff's surgeon.

60. The Pinnacle Device, like the one found in Plaintiff, at the time it left the possession of Defendants, was inherently dangerous for its intended use and was an unreasonably dangerous product which presented and constituted an unreasonable risk of danger and injury to Plaintiff as follows:

i. The Pinnacle Device was sold in a defective condition by design and manufacture;

ii. The Pinnacle Device was insufficiently tested;

iii. The Pinnacle Device as designed and manufactured was unsafe to Plaintiff;

iv. The Pinnacle Device was not accompanied by adequate instructions and/or warnings to fully inform Plaintiff or Plaintiff's physicians of the full nature or extent of the risks associated with its use;

v. The Pinnacle Device as designed and manufactured was unreasonably dangerous to Plaintiff;

vi. The Pinnacle Device did not perform safely as an ordinary consumer/patient, like Plaintiff, would expect;

vii. The Pinnacle Device as designed and manufactured was unsafe for its intended use;

viii. Defendants failed to warn the end user about the dangers and risks of the product;

ix. Defendants knew the component parts of the Pinnacle Device as implemented through design and/or manufacture could cause injury to the end user; and,

x. Any other acts or failures to act by Defendants regarding the studying, testing, designing, developing, manufacturing, inspecting, producing, advertising,

marketing, promoting, distributing, and/or sale of the Pinnacle Devices for hip replacement surgery as will be learned during discovery.

61. Defendants, in continuing to market, sell and distribute the Pinnacle Device after obtaining knowledge it was failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

WHEREFORE, Plaintiffs request a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court, together with costs and interest on that amount at the legal rate from the date of judgment until paid, and other such relief this Court deems just and appropriate.

Third Cause of Action
Strict Products Liability (Design Defect)
(Against All Defendants)

62. Plaintiffs re-allege and incorporate by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

63. At all times mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Pinnacle Device hereinabove described that was surgically implanted in Plaintiff.

64. At all times mentioned herein, the Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed by Defendants was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users such as Plaintiff who had the device surgically implanted.

65. At all times mentioned herein, the Pinnacle Device designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed by Defendants

was in an unsafe, defective, and inherently dangerous condition at the time it left the Defendants' possession.

66. At all times mentioned herein, the Pinnacle Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

67. At all times mentioned herein, the Pinnacle Device's unsafe, defective, and inherently dangerous condition was a cause of injury to Plaintiff.

68. At all times mentioned herein, the Pinnacle Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

69. Plaintiff's injuries resulted from use of the Pinnacle Device that was both intended and reasonably foreseeable by Defendants.

70. At all times mentioned herein, the Pinnacle Device posed a risk of danger inherent in the design which outweighed the benefits of that design.

71. At all times mentioned herein, the Pinnacle Device was defective and unsafe, and Defendants knew, or had reason to know, that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants.

72. Defendants knew, or should have known, at all times herein mentioned, that the Pinnacle Device was in a defective condition, and was and is inherently dangerous and unsafe.

73. At the time of the implantation of the Pinnacle Device into Plaintiff, the aforesaid product was being used for the purposes and in the manner normally intended, namely, for use as a hip replacement device.

74. Defendants, with this knowledge, voluntarily designed their Pinnacle Device in a dangerous condition for use by the public, in particular, Plaintiff.

75. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

76. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product, which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Plaintiff, in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

77. As a direct and proximate result of Defendants' placement of the defective Pinnacle Device into the stream of commerce, Plaintiff experienced, and/or will experience, severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the attendant risk of complications and death from such further surgery.

78. Further, as a result of the foregoing acts and omissions, Plaintiff has, and/or will in the future, suffer a diminished earning capacity.

79. In performing the foregoing acts and omissions, Defendants acted despicably, fraudulently, and with malice and oppression so as to justify an award of punitive and exemplary damages.

WHEREFORE, Plaintiffs request a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court, together with costs and interest on that amount at the legal rate from the date of judgment until paid, and other such relief this Court deems just and appropriate.

Fourth Cause of Action
Failure to Warn
(Against All Defendants)

80. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

81. In the course of business, Defendants designed, manufactured and sold the Pinnacle Device to the hospital for hip replacement surgeries.

82. At the time of the design, manufacture and sale of the Pinnacle Device, and more specifically at the time Plaintiff received the Pinnacle Device, it was defective and unreasonably dangerous when put to its intended and reasonably anticipated use. Further, the Pinnacle Device was not accompanied by proper warnings regarding significant adverse consequences associated with the Pinnacle Device.

83. Defendants failed to provide any warnings, labels or instructions of the Pinnacle Device's dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the product involved significant dangers not readily obvious to the ordinary user of the product.

84. Defendants failed to warn of the known or knowable injuries associated with the malfunction of the Pinnacle Device which would require subsequent surgical procedures and could result in severe injuries.

85. The dangerous and defective conditions in the Pinnacle Device existed at the time it was delivered by the manufacturer to the distributor. At the time Plaintiff had hip replacement surgery, the Pinnacle Device was in the same condition as when manufactured, distributed and sold.

86. Plaintiff did not know at the time of use, nor at any time prior thereto, of the existence of the defects within the Pinnacle Device.

87. Plaintiff suffered the aforementioned injuries and damages as a direct result of Defendants failure to warn.

88. The conduct of Defendants in continuing to market, promote, sell and distribute the Pinnacle Device after obtaining knowledge that the product was failing and not performing as represented and intended, showed a complete indifference to or conscious disregard for the safety of others justifying an award in such sum which will serve to deter Defendants and others from similar conduct.

WHEREFORE, Plaintiffs request a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court, together with costs and interest on that amount at the legal rate from the date of judgment until paid, and other such relief this Court deems just and appropriate.

Fifth Cause of Action
Negligent Infliction of Emotional Distress
(Against All Defendants)

89. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

90. Defendants are liable to Plaintiff for the negligent infliction of emotional distress in the following respect:

a. Plaintiff suffered severe emotional distress, which was as a result of Defendants' negligent conduct in studying, designing, developing, testing, inspecting, manufacturing, producing, advertising, marketing, promoting, distributing, and/or selling of the Pinnacle Device for hip replacement surgery.

b. Plaintiff suffered severe emotional distress, which was as a result of Defendants' negligent conduct in failing to adequately and safely design and construct an

effective and safe Pinnacle Device for hip replacement surgery. Therefore, Defendants are liable to Plaintiff.

91. Defendants' conduct in continuing to market, sell and distribute the Pinnacle Device after obtaining knowledge that it was failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

WHEREFORE, Plaintiffs request a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court, together with costs and interest on that amount at the legal rate from the date of judgment until paid, and other such relief this Court deems just and appropriate.

Sixth Cause of Action
Intentional Infliction of Emotional Distress
(Against All Defendants)

92. Plaintiffs re-allege and incorporate by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

93. Defendants are liable to Plaintiffs for the intentional infliction of emotional distress in the following respect:

a. Plaintiff suffered severe emotional distress, which was as a result of Defendants' extreme, outrageous, intentional, willful, and reckless conduct in studying, designing, developing, testing, inspecting, manufacturing, producing, advertising, marketing, promoting, distributing, and/or sale of the Pinnacle Device for hip replacement surgery.

b. Plaintiff suffered severe emotional distress, which was as a result of Defendants' extreme, outrageous, intentional, willful, and reckless conduct in failing to

adequately and safely design and construct an effective and safe Pinnacle Device for hip replacement surgery, in complete and reckless disregard of the safety of Plaintiff. Therefore, Defendants are liable to Plaintiff.

94. Defendants' conduct in continuing to market, sell and distribute the Pinnacle Device after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

WHEREFORE, Plaintiffs request a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court, together with costs and interest on that amount at the legal rate from the date of judgment until paid, and other such relief this Court deems just and appropriate.

Seventh Cause of Action
Breach of Implied Warranty
(Against All Defendants)

95. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

96. Defendants are liable to Plaintiffs for their breach of implied warranty in the following respect:

a. Defendants sold the Pinnacle Device that was implanted in Plaintiff.

b. Defendants impliedly warranted to Plaintiff, Plaintiff's physicians and health care providers, that the Pinnacle Device was of merchantable quality and safe for the use for which it was intended.

c. Defendants knew or should have known that the Pinnacle Device, at the time of sale, was intended to be used for the purpose of surgically implanting it into the body for hip replacement.

d. Plaintiff, Plaintiff's physicians and health care providers reasonably relied on Defendants' judgment, indications and statements that the Pinnacle Device was fit for such use. When the Pinnacle Device was distributed into the stream of commerce and sold by Defendants, it was unsafe for its intended use, and not of merchantable quality, as warranted by Defendants in that it had very dangerous propensities when used as intended and implanted into a patient's body where it could cause serious injury of harm or death to the end user.

e. Plaintiffs have suffered injuries and damages as a result of Defendants' conduct and actions.

WHEREFORE, Plaintiffs request a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court, together with costs and interest on that amount at the legal rate from the date of judgment until paid, and other such relief this Court deems just and appropriate.

Eighth Cause of Action
Breach of Express Warranty
(Against All Defendants)

97. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

98. At all times herein mentioned, Defendants expressly warranted to Plaintiff and Plaintiff's physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials

intended for physicians, medical patients and the general public, that the aforementioned DePuy Pinnacle Device was safe, effective, fit and proper for its intended use.

99. In utilizing the aforementioned DePuy Pinnacle Device, Plaintiff and Plaintiff's physicians relied on the skill, judgment, representations and foregoing express warranties of Defendants.

100. Said warranties and representations were false in that the aforementioned DePuy Pinnacle Device was not safe and was unfit for the uses for which it was intended.

101. As a result of the foregoing breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

WHEREFORE, Plaintiffs request a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court, together with costs and interest on that amount at the legal rate from the date of judgment until paid, and other such relief this Court deems just and appropriate.

Ninth Cause of Action
Fraud
(Against All Defendants)

102. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

103. In the course of business, Defendants designed, manufactured and sold the Pinnacle Device for hip replacement surgeries.

104. At the time of the design, manufacture and sale of the Pinnacle Device, and more specifically at the time Plaintiff received the Pinnacle Device, it was defective and unreasonably dangerous when put to its intended and reasonably anticipated use. Further the Pinnacle Device was not accompanied by proper warnings regarding significant adverse consequences associated with the product.

105. Defendants were aware of the dangerous and defective condition of the product and intentionally withheld this information from Plaintiff, Plaintiff's physicians, and the general public even though these significant dangers were not readily obvious to the ordinary user of the product, even after a post surgical complication had arisen.

106. Defendants fraudulently presented to Plaintiff, Plaintiff's physicians, and the general public that the Pinnacle Device was a safe and effective product while they were fully aware that the dangerous and defective nature of the Pinnacle Device could and would cause injuries such as those suffered by Plaintiff.

107. Plaintiff and Plaintiff's physicians relied upon the fraudulent misrepresentations and concealments of Defendants, which allowed for the defective Pinnacle Device to be implanted.

108. As a direct and proximate result of Plaintiff's reliance on Defendants' fraudulent misrepresentations and concealments, Plaintiff was seriously and permanently injured.

109. As a direct and proximate result of the acts of the Defendants, Plaintiff has suffered, and will continue to suffer great pain and suffering, mental anguish, and has been otherwise damaged.

110. The conduct of Defendants in continuing to fraudulently market, promote, sell and distribute the Pinnacle Device while fraudulently concealing knowledge that the product was failing and not performing as represented and intended, showed a complete indifference to or conscious disregard for the safety of others justifying an award in such sum which will serve to deter Defendants and others from similar conduct.

WHEREFORE, Plaintiffs request a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court, together with costs and interest on that amount at the legal

rate from the date of judgment until paid, and other such relief this Court deems just and appropriate.

Tenth Cause of Action
Violation of the Texas Deceptive Trade Practices Act
(Tex. Bus. & Com. Code Ann. § 17.41, *et seq*.)
(Against All Defendants)

111. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

112. Defendants unfairly, unconscionably, and deceptively advertised, marketed, sold, and represented the Pinnacle Device as a high quality, safe and effective system to Plaintiff and Plaintiff's physicians.

113. Before they advertised, marketed, sold and represented the Pinnacle Device that was implanted in Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a metal-on-metal total hip replacement system posed to patients like Plaintiff.

114. Plaintiff purchased and used the Pinnacle Device for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection law.

115. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Pinnacle Device, and would not have incurred related medical costs and injury.

116. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Pinnacle Device that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

117. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and,

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

118. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Pinnacle Device. Each aspect of Defendants' conduct combined to artificially create sales of the Pinnacle Device.

119. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the Pinnacle Device.

120. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Pinnacle Device and would not have incurred related medical costs.

121. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, including Plaintiff, constitute unfair and deceptive acts and trade practices in violations of the state consumer protection statutes listed.

122. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or trade practices in violation of state consumer protection statutes.

123. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of Tex. Bus. & Com. Code Ann. § 17.41, *et. seq.*

124. Under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

125. Defendants violated the statutes that were enacted in this state to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Pinnacle device was fit to be used for the purpose for which it was intended, when in fact the device was defective and dangerous, and by other acts alleged herein. The representations were made in uniform promotional materials.

126. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

127. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which hip implant device to use and recommend.

128. Defendants' deceptive, fraudulent and unconscionable representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

129. By reason of the unlawful acts engaged in by Defendants, and as a proximate result thereof, Plaintiffs has suffered ascertainable losses and damages.

130. As a direct and proximate result of Defendants' violations of the state's consumer protection laws, Plaintiff has sustained economic losses and other damages, and is entitled to statutory and compensatory damages in an amount to be proven at trial.

131. As specifically described in detail above, Defendants knew that the Pinnacle Device subjected patients to early failure, painful and harmful physical reactions to toxic metallic particles and ions, death of tissue, bone loss, and the need for explants and revision surgery.

132. As a direct and proximate result of Defendants' representations, Plaintiff has experienced and/or will experience significant damages, including but not limited to, permanent physical injury, economic loss, pain and suffering and the need for revision surgery to repair the damage caused by the Pinnacle Device.

WHEREFORE, Plaintiffs request a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court, together with costs and interest on that amount at the legal rate from the date of judgment until paid, and other such relief this Court deems just and appropriate.

Eleventh Cause of Action
Punitive Damages
(Against All Defendants)

133. Plaintiffs re-allege and incorporate by reference all preceding paragraphs as if fully set forth herein.

134. The acts and/or omissions of Defendants as set forth, *supra*, were knowing and willful failures to warn of the failures of the product and lack of efficacy and risks, and they constitute malicious, willful, wanton, and/or reckless conduct.

135. The Defendants knew or should have known that their product failed at a high rate. Nevertheless, they continued to market the product by providing false and misleading information with regard to safety and efficacy.

136. At all times relevant herein, Defendants:

a. Knew the product was dangerous;

b. Concealed the dangers and health risks from Plaintiff, Plaintiff's physician and the public at large;

c. Made misrepresentations to Plaintiff, Plaintiff's physicians, and the public in general as previously delineated herein, as to the safety and efficacy of the product;

d. Failed to inform, and otherwise mislead, the FDA as to the failure rate and dangers of the Pinnacle Device.

137. Defendants' acts were willful, wanton and malicious, and showed a total disregard for human life and human suffering. Based upon the acts alleged herein, Defendants knew or should have known, that the very patients whose lives were supposed to be improved by the hip implants would instead be subject to enhanced pain and suffering, as well as duplicative and unnecessary surgeries, and that their conduct would naturally and probably result in injury and damage. Defendants continued such conduct with malice, and/or reckless disregard of the consequences from which the malice may be inferred. Plaintiffs should be awarded punitive damages against Defendants based upon the acts herein, so as to punish Defendants and deter similar conduct by Defendants.

Twelfth Cause of Action
Loss of Consortium
(Against All Defendants)

139. Plaintiffs re-allege and incorporate by reference each and every allegation contained in paragraphs as though fully set forth herein.

140. Plaintiff NANCY LYNCH is, and at all times relevant hereto, has been the lawful spouse of Plaintiff KENNETH DOYLE LYNCH, and as such she is entitled to the comfort and enjoyment of his society and services.

141. As a direct and proximate result of the foregoing misconduct of the Defendants, Plaintiff NANCY LYNCH has been deprived of her spouse's companionship, services, solace, consortium, affection and attention to which she is entitled.

142. As a result of the foregoing, Plaintiff NANCY LYNCH has been and will continue to be injured and damaged.

WHEREFORE, Plaintiffs request a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court, together with costs and interest on that amount at the legal rate from the date of judgment until paid, and other such relief this Court deems just and appropriate.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

a. Judgment in favor of Plaintiffs and against all Defendants, for damages in such amounts as may be proven at trial;

b. Compensation for both economic and non-economic losses, including but not limited to medical expenses, disfigurement, pain and suffering, mental anguish and emotional distress, in such amounts as may be proven at trial;

c. Punitive and/or exemplary damages in such amounts as may be proven at trial;

d. Attorneys' fees and costs;

e. Pre-and post-judgment interest; and

f. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

Dated: July 14, 2015

Respectfully submitted,

By: s/ John C. Duane

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